DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 25, 2014

Mortara Instrument, Inc.
Amy Yang
Sr. Regulatory Affairs Engineer
7865 North 86th St.
Milwaukee, Wisconsin 53224

Re: K133989
Trade/Device Name: Ambulo 2400 Ambulatory Blood Pressure Monitoring System
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 13, 2014
Received: October 15, 2014

Dear Amy Yang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133989

Device Name
Ambulo 2400 Ambulatory Blood Pressure Monitor

Indications for Use *(Describe)*
The Ambulo 2400 Ambulatory Blood Pressure Monitor is indicated for use in adult & pediatric patient populations; it is not indicated for use with neonates.

The Ambulo 2400 Ambulatory Blood Pressure Monitor is designed to measure systolic and diastolic blood pressure and pulse rate of adults and pediatric patients, using the oscillometric method on a cuffed arm.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Abbreviated 510(k) Notification

510(k): Ambulo 2400 Device Summary

Submitter: **Date: November 25, 2014**

Amy Yang, Sr. Regulatory Affairs Engineer
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
FAX: (414) 354-4760
Phone: (414) 354-1600
Contact: Amy Yang (see above)

Trade Name: Mortara Ambulo 2400 Ambulatory Blood Pressure Monitor
Common Name: Ambulatory Blood Pressure Monitoring System
Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
Classification Description: Noninvasive blood pressure measurement system
Classification Regulation: 21 CFR §870.1130
Product Code: DXN

Legally marketed devices to which S.E. is claimed:

Mortara Ambulo 2400	Predicate 510(k) Number	Predicate Manufacturer / Model
System, Measurement, Blood-Pressure, Non-Invasive	K080274	Tiba Medical / Ambulo 2400

Description:

The Ambulo 2400 is a compact, lightweight, non-invasive ambulatory blood monitoring system. The Ambulo 2400 can measure systolic and diastolic blood pressure, mean arterial pressure and pulse rate over a 24 hour period. It is easily configured and individually-fitted for each patient by a physician or health care professional. Measurements are automatically captured, without medical supervision, by the Ambulo 2400 and later downloaded to a computer for analysis and interpretation by a physician.

Since blood pressure naturally fluctuates throughout a full day according to various factors, such as sleep patterns, medication, diet, exercise and stress, a single measurement is not sufficient to make a sound diagnosis. Analyzing a person's blood pressure over an extended period of time can improve the diagnosis and ultimately the treatment. The Ambulo 2400 can collect blood pressure data under a variety of daily activities over a 24 hour period and then downloaded to a computer for analysis and treatment. The Ambulo 2400 may also be use on an ongoing basis to evaluate the effectiveness of a prescribed treatment.

Technology Comparison:

The Mortara Ambulo 2400 utilizes the same or similar technology for each parameter as utilized by the predicate device.

Intended Use:

The Ambulo 2400 is intended to be a compact, non-invasive Ambulatory Blood Pressure Monitoring (ABPM) system. ABPM technology involves the use of an automatic, non-invasive device to measure blood pressure over an extended period of time – typically 24 hours. The ABPM procedure is an essential tool for physicians, clinical researchers, and other healthcare professionals to analyze a patient's blood pressure as it relates to his/her circadian rhythm. This process offers insight into diagnostic factors as they relate to the spectrum of activity within everyday life.

Indications for Use:

The Ambulo 2400 Ambulatory Blood Pressure Monitor is indicated for use in adult & pediatric patient populations; it is not indicated for use with neonates.

The Ambulo 2400 Ambulatory Blood Pressure Monitor is designed to measure systolic and diastolic blood pressure and pulse rate of adults and pediatric patients, using the oscillometric method on a cuffed arm.

Standards and Testing:

Performance testing has been completed on the Mortara S4 Mobile Monitor and demonstrates compliance with International and FDA-recognized consensus standards:

IEC 60601-1-1:2000 – Medical electrical equipment Part 1: General requirements for basic safety and essential performance. Collateral Standard: Safety Requirements for Medical Electrical Systems.

IEC 60601-1-2:2007 – Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility.

IEC 60601-1-4 Consol. Ed. 1.1:2000 – Medical Electrical Equipment – Part 1-4: General requirements for Collateral Standard: Programmable Electrical Medical Systems.

IEC 60601-1-6:2004 – Medical Electrical Equipment – Part 1-6: General Requirements for Safety and Essential Performance – Collateral Standard: Usability.

IEC 60601-1-6:2010 – Medical Electrical Equipment – Part 1-6: General Requirements for Safety and Essential Performance – Collateral Standard: Usability.

IEC 60601-2-30:1999 – Medical Electrical Equipment. Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

IEC 80601-2-30:2009+A1:2013 – Medical Electrical Equipment. Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

IEC/EN 62304:2006+AC:2008 – Medical device software - Software life-cycle processes.

IEC 62366:2007 – Medical devices - Application of usability engineering to medical devices.

ISO 14971:2007 – Medical devices – Application of Risk Management to Medical Devices

AAMI/ANSI SP10:2002/ 2008 & AAMI SP10:2002/A1:2003 – Manual, electronic or automated sphygmomanometers.

Additionally, verification, validation, performance and environmental tests have been performed to address the intended use, requirement specifications, usability and risk management requirements.

Performance Testing:

Sterilization Validation:
The Mortara Ambulo 2400 is not sterilized or sterilizable, and therefore this section does not apply to the device itself.

Shelf Life Testing:
The Mortara Ambulo 2400 is not sterilized or sterilizable, and therefore this section does not apply to the device itself.

Biocompatibility Testing:
The cuffs used are parts of the system that come in contact with the patient. These component devices have been previously tested in their own right for other submissions and found to be acceptable. However, the Ambulo 2400 itself does not involve direct / indirect patient contact.

Software Testing:
Software for the Mortara Ambulo 2400 was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Mortara Ambulo 2400 complies with its predetermined specification.

Electrical Safety:
The Mortara Ambulo 2400 was evaluated for patient safety in accordance with applicable Standards.

Electromagnetic Compatibility Testing:
The Mortara Ambulo 2400 was tested for EMC in accordance with applicable Standards. Test results indicated that the Mortara Ambulo 2400 complies with its predetermined specification.

Performance Testing – Bench:
The Mortara Ambulo 2400 was tested in accordance with internal requirements and procedures, and test results indicated that the device complies with the predetermined requirements. This testing includes performance and functional.

Performance Testing – Animal:
Animal performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara Ambulo 2400.

Performance Testing – Clinical:
The Ambulo 2400 was evaluated for clinical performance to demonstrate safety and effectiveness.

Conclusion:
The results of these activities demonstrate that the Mortara Ambulo 2400 is as safe, as effective and performs as well as or better than the predicate device.